



SEVERE ACUTE RESPIRATORY SYNDROME

FACT SHEET

Fact Sheet for Clinicians: Interpreting SARS Test Results from CDC and Other Public Health Laboratories

Information regarding SARS laboratory testing may change. For the most current information and up-to-date version of this document, see www.cdc.gov/ncidod/sars/testresultsc.htm

The Centers for Disease Control and Prevention (CDC) and other laboratories have been working to investigate and control the spread of severe acute respiratory syndrome (SARS). Information on SARS, including the case definition and infection control guidelines, is available at www.cdc.gov/ncidod/sars.

The cause of SARS has been determined to be infection with a previously unrecognized human coronavirus, called SARS-associated coronavirus (SARS-CoV). Scientists from CDC and other institutions have published reports in peer-reviewed journals describing the isolation and characterization of SARS-CoV and its association with SARS. Although these reports provide strong evidence that this new coronavirus is the etiologic agent of SARS, it is possible that other pathogens might have a role in some cases of SARS.

CDC and others have developed new tests for detecting SARS-CoV. Using these tests, CDC has identified evidence of SARS-CoV infection in several U.S. residents. Following are some key issues that clinicians providing care for patients with SARS may find useful when interpreting SARS-CoV testing results. (Note: information about laboratory tests for SARS-CoV and the interpretation of results from these tests may change. Please check the CDC website for the most up-to-date version of this fact sheet at www.cdc.gov/ncidod/sars/testresultsc.htm.)

What tests for SARS CoV are being done and which results are being reported?

At this time, tests for SARS-CoV are still being refined, and the sensitivity and specificity are uncertain and still being evaluated. It also is not known which tests perform best at which time points after onset of a patient's illness. Several types of newly developed tests are being used to test for SARS-CoV:

1. Serum antibody tests, including both enzyme immunoassay (EIA) and indirect fluorescent-antibody (IFA) formats, have been developed. State public health laboratories are using the EIA. At this time, CDC is interpreting positive test results to indicate previous infection with SARS-CoV. However, some people do not test positive until more than 21 days after onset of illness. Therefore, a negative test result can be considered a true negative only if the specimen was collected more than 21 days after the patient's onset of illness. For patients with a negative antibody test result whose specimens were obtained 21 or fewer days after illness onset, an additional antibody test should be done on a specimen drawn more than 21 days after onset to determine if they are negative or positive for SARS-CoV. The recommended timing of the second sample may be adjusted as more information becomes available.
2. Reverse transcription-polymerase chain reaction (RT-PCR) testing is also available. This test can detect SARS-CoV RNA in clinical specimens, including serum, stool, and nasal secretions.
3. Viral isolation for SARS-CoV also has been done. In these studies, clinical specimens from SARS patients are co-cultured with well-characterized cell lines, and then laboratorians look for evidence of SARS-CoV replication in these cultured cells.

Fact Sheet for Clinicians: Interpreting SARS Test Results from CDC and Other Public Health Laboratories

(continued from previous page)

The number of tests that can be done is limited by the amount and type of specimens and the test type. If there is sufficient specimen, both antibody testing and the RT-PCR are done. Viral isolation is the most difficult and time-consuming test and cannot be done on all patients.

What does it mean if a patient with SARS has a positive test result for SARS-CoV?

A positive test result suggests that the patient with SARS has or recently had an infection with SARS-CoV. However, it is possible that a positive test result could be incorrect ("false-positive"). As the tests are improved, CDC may re-test specimens from SARS patients with positive results, and results from these improved tests might be negative.

What does it mean if a patient with SARS has a negative test result for SARS-CoV?

Some patients with clinical and epidemiologic criteria that meet the case definition for SARS (see www.cdc.gov/ncidod/sars/casedefinition.htm) may have negative test results for SARS-CoV. There are several possibilities to explain negative test results for SARS-CoV:

1. The patient did not have an infection with SARS-CoV. The patient may have a SARS-like illness caused by other viruses or infectious agents. It can sometimes be difficult to find out which infectious agent is causing a person to be ill with fever, respiratory symptoms, and pneumonia. For example, only about half of all diagnosed cases of pneumonia have a specific etiologic agent detected.
2. The test results may be incorrect ("false-negative"). As the tests are improved, CDC may re-test specimens from SARS patients with negative test results. Results from more-sensitive, improved tests might be positive.
3. The samples were not obtained at a time point in the course of SARS-CoV infection when test results are positive. The RT-PCR result will be positive only if there is viral RNA in the specimen. This may be for a fairly brief period, depending on which specimen (e.g., serum, stool, nasal secretions) was tested. The antibody tests may not become positive until more than 21 days after illness onset and possibly longer.

What does it mean if the test results are positive for human metapneumovirus?

CDC has tested some specimens from SARS patients for a variety of viruses, including human metapneumovirus. Human metapneumovirus is a recently recognized virus that belongs to the paramyxovirus family of viruses, which cause a broad range of respiratory and childhood illnesses, including mumps, measles, and croup. Human metapneumovirus is genetically related to respiratory syncytial virus, a common cause of lower respiratory tract infection in children. Several laboratories have reported positive test results for human metapneumovirus in some patients with SARS. There is not enough information to determine what role, if any, human metapneumovirus might have in some cases of SARS.

Should a patient with SARS who has negative SARS-CoV test results continue with the isolation precautions recommended by CDC and other public health authorities?

As noted above, the interpretation of negative SARS-CoV test results can vary depending on which test was performed and when the testing was done. CDC advises that isolation precautions for SARS patients should be continued even if laboratory test results for SARS-CoV are negative. This recommendation is subject to change. Evaluating physicians may wish to consult their local public health authorities for advice on interpretation of SARS-CoV test results. Physicians can also check the CDC Web site for the most recent information on the interpretation of SARS-CoV laboratory results.

All SARS patients should limit interactions outside the home and should not go to work, school, out-of-home childcare, or other public areas until 10 days after resolution of fever and respiratory symptoms.

June 2, 2003

Page 2 of 3

Fact Sheet for Clinicians: Interpreting SARS Test Results from CDC and Other Public Health Laboratories

(continued from previous page)

During this time, the infection control precautions for SARS patients should be followed (see www.cdc.gov/ncidod/sars/ic-closecontacts.htm).

Has the new information about SARS-CoV changed the recommendations for medical treatment for patients with SARS?

The discovery that SARS-CoV is the cause of SARS has not changed treatment recommendations (see CDC's SARS website for treatment information at www.cdc.gov/ncidod/sars/treatment.htm). The new coronavirus is being tested against various antiviral drugs to see if an effective treatment can be found.

Should a person who traveled to an area where there is community transmission (see the case definition at www.cdc.gov/ncidod/sars/casedefinition.htm) of SARS or who had contact with a SARS patient be tested even if not ill?

People who have potentially been exposed to SARS patients should not be tested unless the CDC or their state health department specifically asks them to be part of one of the ongoing SARS investigations. We do not yet know how to interpret the results of testing of persons who are not ill.

What other investigations related to SARS are planned?

The state health department or CDC may contact some SARS patients regardless of whether the SARS-CoV test result was positive or negative. These patients might be asked to participate in investigations that are trying to find out more about the new coronavirus and SARS and how they are related to each other. If a patient agrees to take part in those investigations, his or her permission would be requested to collect more specimens for testing. Participation is voluntary.

For more information, visit www.cdc.gov/ncidod/sars or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

June 2, 2003

Page 3 of 3